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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT

PAPER NUMBER

1775

NOTIFICATION DATE

DELIVERY MODE

11/17/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

OfficeAction25944@oliff.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/815,874	<b>Applicant(s)</b> SCHEIN ET AL.	
	<b>Examiner</b> NATHAN A. BOWERS	<b>Art Unit</b> 1775	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) 27-46, 56 and 61-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26, 47-50, 52-54, 57, 59, 60 and 64 is/are rejected.
- 7) ☒ Claim(s) 51, 55 and 58 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Newly submitted claims 56 and 61-63 are directed to an invention that is independent or distinct from the invention elected in the response filed 07 March 2008. Accordingly, claims 56 and 61-63 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Objections***

Claim 60 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Claim 60 recites the same limitations as previously set forth in claim 50.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1-8, 11-22, 26, 47-54, 57, 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hassanein (US 6046046) in view of Dennehey (US 5462416).

With respect to claims 1-3, 7, 15 and 47, Hassanein discloses an apparatus for holding an organ comprising a portable housing (Figure 1:20) for enclosing the organ and a first set of tubes (Figure 2:54, 58, 64, 124). This is disclosed in column 8, lines 21-42 and throughout the reference. These tubes within the portable housing are connected to a separate set of corresponding delivery tubes using ports (Figure 5:292) arranged at the top of the portable housing. Hassanein, however, does not expressly state that the portable housing is reversibly connectable to a tube frame.

Dennehey discloses a removable tube frame assembly (see Figure 2:26) for holding a plurality of tubes at predetermined positions where they are directly connectable to various containers (Figure 2:20) and chambers (Figure 2:16). Smaller tube frame assemblies (Figure 3:22) are provided within the larger tube frame assembly (see also Figures 4-9) in order to further reroute a fluid moving through tubes within the larger tube frame assembly.

Hassanein and Dennehey are analogous art because they are from the same field of endeavor regarding blood and medical fluid transport and processing systems.

At the time of the invention, it would have been obvious to collect and arrange the tubes extending from the portable housing (20) of Hassanein using a tube frame similar to that disclosed by Dennehey. One of ordinary skill would have recognized that the tubes emerging from the top of the Hassanein portable housing are largely unorganized (see Figures 1 and 4-6), and therefore would have been motivated to consolidate and manage them using a tube frame in order to prevent tangling or damage. As evidenced by Dennehey, it is known in the art to provide a tube frame adjacent to a chamber or processing station to organize and position the fluid transporting tubes that directly connect to associated tubes within said chamber or processing station.

With respect to claims 4 and 5, Hassanein and Dennehey disclose the apparatus in claim 1. Hassanein further teaches in column 17, lines 3-20 that a soft pad (Figure 5:218) is provided for supporting an organ or tissue within an organ bath (Figure 5:212).

With respect to claim 6, Hassanein and Dennehey disclose the apparatus in claim 1. Hassanein additionally indicates that a filter (Figure 4:46) is in communication with tubing adapted to supply and withdraw fluid to and from the organ. This is described in column 8, lines 16-20.

With respect to claim 8, Hassanein and Dennehey disclose the apparatus in claim 1 wherein a pressure sensor capable of determining fluid pressure is connectable to the tube frame. Hassanein discloses the use of a control unit capable of detecting and regulating fluid pressure in column 18, line 12 to column 19, line 22.

With respect to claims 11 and 12, Hassanein and Dennehey disclose the apparatus in claim 1 wherein the plurality of tubes in the portable housing are connectible to an organ. This is depicted in at least in Figures 1, 2 and 5.

With respect to claims 13, 14, 17 and 22, Hassanein and Dennehey disclose the apparatus in claim 1. Furthermore, Hassanein teaches that the portable housing is reversibly attached to a plurality of external delivery tubes using various connectors (Figure 8:426) that regulate flow from the external tubes to the tubes within the portable housing. This connector is functionally equivalent to a clip, pin or snap in that it presses the portable housing tightly against an adjacent structure. Screws are considered to be well known means that would serve to hold a chamber or container in place.

With respect to claim 16, Hassanein and Dennehey disclose the apparatus in claim 1. Hassanein further teaches that the portable housing (Figure 1:20) is configured to be received by an organ diagnostic/transporter device (Figure 4:140) in the form of a analysis cart.

With respect to claims 18-21, Hassanein and Dennehey disclose the apparatus in claim 17 wherein a pump is provided for transporting fluids through the plurality of tubes found in the portable housing and the tube frame. This is described in column 7, lines 33-52 and throughout the reference. The use of conventional peristaltic type pumps (i.e. roller pumps) is additionally considered to be notoriously well known in the art.

With respect to claim 26, Hassanein and Dennehey disclose the apparatus in claim 1. Plastic is considered to be a well known material suitable for the construction of a tube frame. One of ordinary skill in the art would have been motivated to utilize plastic in the construction of the Hassanein tube frame due to its low cost and compatibility with known shaping techniques.

With respect to claims 48-53, 57 and 60, Hassanein and Dennehey disclose the apparatus in claims 1 and 47. Additionally, Hassanein indicates in Figure 5 that the openings of the portable housing are configured to be horizontally aligned on a same

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horizontal plane. Furthermore, Dennehey teaches in Figure 12 that the tubes within the tube frame are horizontally aligned on the same horizontal plane. When the Dennehey tube frame is used in combination with the Hassanein portable housing, one of ordinary skill would have found it obvious and logical to align the tube frame and the openings of the portable housing adjacent to each other and on the same horizontal plane.

With respect to claims 54 and 59, Hassanein and Dennehey disclose the apparatus in claims 1 and 47. In Figure 5, it is apparent that the various openings provided on the top surface of the Hassanein apparatus are generally horizontally aligned on the same horizontal plane. One of ordinary skill would additionally have found it obvious to provide the tube frame of Dennehey on a support arranged along the same horizontal plane. One of ordinary skill would have understood that the functionality of the Hassanein system would be maintained regardless of whether the tube frame assembly was added below the portable housing or at a location horizontally aligned with the portable housing.

2) Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hassanein (US 6046046) in view of Dennehey (US 5462416) as applied to claim 1, and further in view of Toledo-Pereyra (US 4186565).

Hassanein and Dennehey disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly state that a bubble trap is provided within the tube frame.



Toledo-Pereyra discloses an apparatus for holding an organ (Figure 2:K) comprising a portable housing (Figure 2:14) defining one or more openings and a tube frame (Figure 2:15) removably connectible to the portable housing. Column 1, line 51 to column 2, line 60 indicates that fluids located within the tube frame are transported to the portable housing using a system of tubes. The plurality of tubes in the tube frame are in communication with a plurality of tubes located within the portable housing in order to effectively introduce and withdrawn fluid to and from the organ. Furthermore, Toledo-Pereyra discloses that a bubble trap (Figure 2:17) is connectable to the tube frame and in communication with tubes located in the portable housing and the tube frame.

Hassanein and Toledo-Pereyra are analogous art because they are from the same field of endeavor regarding tissue treatment systems.

At the time of the invention, it would have been obvious to provide the tube frame of Hassanein with a bubble trap capable of treating fluid upstream from the portable housing holding the organ/tissue. As evidenced by Toledo-Pereyra, bubble traps are common components of an organ perfusion system, and fulfill the function of removing undesirable gases from a fluid stream before addition to the culture chamber. One of ordinary skill would have readily recognized the benefits of using a bubble trap when operating the Hassanein device, and would have been able to incorporate the bubble trap into the system of Hassanein in a predictable manner.

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3) Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hassanein (US 6046046) in view of Dennehey (US 5462416) as applied to claim 17, and further in view of Fahy (US 5586438).

Hassanein and Cannon disclose the apparatus set forth in claim 17 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly state that a sensor is provided for detecting proper and improper connection between the tube frame and the organ transporter.

Fahy discloses a lid position sensor capable of detecting when the lid of the organ holding chamber is ajar. Column 13, lines 16-35 state that when the lid is determined to be in an undesirable position, the sensors will convey this information to an operator through the use of an alarm or visual display.

Hassanein and Fahy are analogous art because they are from the same field of endeavor regarding organ/tissue perfusion systems.

At the time of the invention, it would have been obvious to include a detection system capable of determining when the tube frame of Hassanein is improperly connected to the organ transporter. This would have been beneficial because it would have prevent possible damage to the organ resulting from mechanical failures resulting from improper connections. By ensuring that each component is properly connected to the other components, one would have been able to prevent tampering with the organ or excessive heat or contaminant infiltration.

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4) Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fahy (US 5586438) in view of Hassanein (US 6046046).

Fahy discloses an apparatus for holding an organ or tissue comprising a portable housing (see Figure 1). Tubes are enclosed within the portable housing and also positioned external to the portable housing. See at least Figure 1:119 and Figure 1:110. From Figures 1 and 3, it is apparent that the tubes form a closed circuit, and that the portable housing may be installed in and removed from an organ transporter without breaking the closed fluid circuit. Fahy, however, does not expressly state that the tubes are divided into a distinct first set of tubes and a distinct second set of tubes.

Hassanein discloses an apparatus for holding an organ comprising a portable housing (Figure 1:20) for enclosing the organ and a first set of tubes (Figure 2:54, 58, 64, 124). This is disclosed in column 8, lines 21-42 and throughout the reference. These tubes within the portable housing are connected to a separate set of corresponding delivery tubes using ports (Figure 5:292) arranged at the top of the portable housing.

Fahy and Hassanein are analogous art because they are from the same field of endeavor regarding organ/tissue perfusion systems.

At the time of the invention, it would have been obvious to divide the Fahy tube system into a first set of tubes retained within the portable housing and a distinct second set of tubes retained external to the portable housing. As evidenced by Hassanein, it is well known in the art to connect a first tube to a second tube using a common connection port located along the wall of a portable housing. One of ordinary skill would

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have recognized the mere separation of the existing Fahy tube system into a plurality of discrete parts as an obvious alternative fluid delivery and withdrawal means.

### ***Double Patenting***

Claim 57 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 49. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Allowable Subject Matter***

Claims 51, 55 and 58 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

With respect to claim 51, the prior art does not disclose, in the claimed environment, an apparatus for holding an organ comprising a portable housing having a first set of tube segments in communication with a second set of tube segments positioned within a tube frame, wherein one or more openings of the portable housing are on a side surface of the portable housing and are horizontally aligned on a same horizontal plane with the second set of tube segments located within the tube frame.

With respect to claims 55 and 58, the prior art does not disclose, in the claimed environment, an apparatus for holding an organ comprising a portable housing having a

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first set of tube segments in communication with a second set of tube segments positioned within a tube frame, wherein the first and second set of tube segments create a closed circuit that is not broken when the portable housing is installed in and removed from an organ transporting/perfusion/diagnostic device.

### ***Response to Arguments***

Applicant's arguments filed 21 September 2010 with respect to the 35 U.S.C. 103 rejections regarding the combination of Hassanein and Dennehey have been fully considered but are not persuasive.

*Applicant's principle arguments are*

*(a) Hassanein's tubes are already organized, and further use of a tube frame is unnecessary. A tube frame would interfere with Hassanein's requirement that various tubes are provided at specific elevations and are connected to the portable housing at specific locations.*

In response, please consider the following remarks.

One of ordinary skill would have recognized that the addition of a tube frame would not have prevented the afterload line 60 and the line connected to filter 46 from remaining freely adjustable in height above the portable housing. For example, the tube frame could be positioned underneath the portable housing or at a height horizontally aligned with the portable housing without interfering with how tubes are arranged above the portable housing. Furthermore, a tube frame provided at either of these locations

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would still provide the benefit of sorting tubes so that they do not become tangled or damaged.

*(b) A tube frame added on Hassanein's lower shelf would not be adjacent to the portable housing as required by the claims.*

In response, please consider the following remarks.

During prosecution, claims language is given its broadest reasonable interpretation in light of the specification. The term "adjacent" is interpreted to read on a tube frame provided on Hassanein's lower shelf because, at this location, the tube frame is still relatively close to the portable housing.

*(c) As tentatively agreed during the personal interview, Hassanein and Dennehey fail to disclose the features of claim 49.*

In response, please consider the following remarks.

It was the Examiner's understanding that the tentative agreement related to the features of claim 51, rather than claim 49. Hassanein and Dennehey fail to disclose openings on the side surface of the portable housing horizontally aligned with each other as well as the tubes within the tube frame. See Allowable Subject Matter above.

### **Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571)272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/  
Primary Examiner, Art Unit 1775

/Nathan A Bowers/  
Examiner, Art Unit 1775